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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,026	12/05/2003	Steven F. Bolling	FORFLOW.ICP6C1	8833
20995	7590	12/15/2004		
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER LAYNO, CARL HERNANDZ	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

10/729,026

Applicant(s)

BOLLING ET AL.

Examiner

Carl H. Layno  
12/11/04

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/5/03, 4/5/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for priority filing as a Continuation of U.S. Application Serial No. 10/289,467, filed on November 6, 2002, which is a Continuation-In-Part (CIP) of U.S. Patent No. 6,685,621, which is a CIP of U.S. Patent No. 6,610,004, which is a CIP of U.S. Patent No. 6,390,969, which is a CIP of U.S. Patent No. 6,387,037, which is a CIP of U.S. Patent No. 6,428,464, which is a CIP of U.S. Patent No. 6,200,260, which claims benefit of U.S. Provisional Application Serial No. 60,061,434, filed October 9, 1997.

### *Information Disclosure Statement*

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on December 5, 2003 and on April 5, 2004.

### *Drawings*

3. Applicant's formal drawings were received by the Office on December 5, 2003 and have been approved by the Examiner.

### *Specification*

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means"

Art Unit: 3762

and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In this case, the Abstract is over 200+ words in length and should be reduced to less than 150 words.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Barbut '356 (Applicant's Prior Art).

Art Unit: 3762

The Barbut '356 patent, cited by the Applicant as prior art, describes a medical device (Fig. 5B) for augmenting blood flow to the heart including the feature of an implantable catheter 33 (Fig. 5A), which performs the function of applicant's claimed conduit. Catheter 33 includes two tubular members 1,2 which are inserted into the patient's vasculature and a blood pump 35. In use, blood is input into tubular member 1 from the patient's left carotid artery (col.7, lines 20-40) and moved by blood pump 35 through a second tubular member 2 to the contralateral carotid artery. Blood moves in reverse directions through catheter conduit section 33. The tubular members 1,2 of Barbut are equipped with balloon occluders whose expansion may control blood flow rate (col.3, lines 59-62). This would presumably include blood flow rates both faster and slower than normal. Although applicant's earliest priority filing date is October 9, 1997, the concept of a single conduit having two lumens, carrying blood in reverse directions does not appear until the filing of U.S. Application Serial No. 09/470,841, now U.S. Patent No. 6,387,037 on December 23, 1999. Barbut's earliest priority filing date is January 15, 1999, which pre-dates this date.

### ***Double Patenting***

7. Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/078,283. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims recite the elements of a pump capable of generating average subcardiac blood flow rates which are "substantially below that of the patient's heart when healthy" and a conduit/multi-lumen catheter with two ends inserted into the patient's vasculature.

Art Unit: 3762

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

8. Claim 4 is allowed.

9. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 4 describes elements of systems for supplementing blood circulation in a patient in which a pump is specified as pumping blood at “subcardiac flow rates” having average flow rates that are “substantially below that of the patient’s heart when healthy” and specifying a conduit in which “blood may travel in reverse directions”. The Barbut ‘356 does not meet these specific details. Lacking any other reference(s) in the prior art, which show this combination of claimed details, the Examiner deems these claims to be allowable.

10. As allowable subject matter has been indicated, applicant’s reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a). Specifically, **corrected formal drawings are required**.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant’s disclosure.

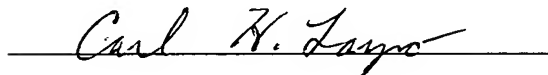
Art Unit: 3762

The McGinnis '263 and Child '941 are cardiac pumps which appear to be useful in pumping blood in reverse directions (bi-directionally). Unlike applicant's device, no teaching is present for using these with a single conduit capable of passing blood in two directions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (571) 272-4955. All faxed correspondence should be sent to the Office's official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (571) 272-4399.



**CARL LAYNO**  
**PRIMARY EXAMINER**

CHL  
12/11/2004